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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,487	10/31/2006	Volker Schehlmann	4804-6	3196

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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,487	SCHEHLMANN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *23 and 24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/20/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-22), phenylbutyric acid and retinol in the reply filed on March 4, 2009 is acknowledged.

Claims 23 and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-3 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gudas et al (WO 02/060430 A1, listed on IDS filed September 20, 2006).

Claims 1-3 and 11-13 are drawn to a composition comprising an HDAC inhibitor and a retinoid.

Gudas et al (WO 02/060430 A1, listed on IDS filed September 20, 2006) teaches a composition comprising a solution of the retinoid, retinoic acid, the HDAC inhibitor, sodium phenylbutyrate, and ethanol p. 8, line 17 through p. line 13 and Figure 1). The sodium ion would necessarily dissociate from the phenylbutyric acid in solution, leaving the free acid as the active agent. Additionally, with regard to the intended use limitations of claims 11-13, a recitation of the intended use of the claimed invention must result in a

structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the instantly claimed composition is structurally indistinct from the composition of Gudas et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas et al (WO 02/060430 A1, listed on IDS filed September 20, 2006).

Claims 1-4 and 6-13 are drawn to a composition comprising phenylbutyric acid and retinol.

Gudas et al (WO 02/060430 A1) teaches a composition comprising sodium phenylbutyrate, retinol and a pharmaceutically acceptable carrier (p. 4, line 29, p. 5, lines 2 and 18-29). Gudas et al does not explicitly teach the use of the free acid form (i.e. phenylbutyric acid); however it would have been obvious to one of ordinary skill in the art to use the free acid form or the salt, since both forms would have been reasonably expected to have the same or substantially similar therapeutic benefit and additionally sodium phenyl butyrate is administering in solution, as prepared at pages 9-10, where the sodium ion would necessarily dissociate, leaving the free acid as the active agent. Gudas et al does not explicitly teach the concentrations and ratios specified in claims 6-10; however Gudas et al does teach that dosages of the compounds vary based on several factors including the age, weight, condition of patient, etc. (p. 15, lines 15-23). It is obvious from the above teachings that Gudas et al expressly contemplates variation in the dosage amounts of the active agents and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the concentrations

and ratios of composition components that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed. Additionally, with regard to the intended use limitations of claims 11-13, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case the instantly claimed composition is structurally indistinct from the composition of Gudas et al.

Claims 5 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gudas et al (WO 02/060430 A1, listed on IDS filed September 20, 2006) in view of Collier et al (WO 01/10427 A2).

Gudas et al (WO 02/060430 A1) teaches the aforementioned composition, useful in the treatment of skin cancer and further teaches that said composition can be administered by any medically acceptable route (p. 6, lines 24 and 25). Gudas et al does not explicitly teach the composition as a topical composition.

Collier et al teaches that topical formulations are useful in the treatment of skin cancer (p. 4, lines 10-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instantly claimed invention to formulate the composition of Gudas et al as a topical formulation, since Gudas et al teaches that the composition is useful in the treatment of skin cancer and can be administered by any medically acceptable route

and Collier et al teaches that topical formulations are useful in the treatment of skin cancer, thus resulting in the instantly claimed composition with a reasonable expectation of success. Gudas et al does not explicitly teach the use of the free acid form (i.e. phenylbutyric acid); however it would have been obvious to one of ordinary skill in the art to use the free acid form or the salt, since both forms would have been reasonably expected to have the same or substantially similar therapeutic benefit and additionally sodium phenyl butyrate is administering in solution, as prepared at pages 9-10, where the sodium ion would necessarily dissociate, leaving the free acid as the active agent. Gudas et al does not explicitly teach the concentrations and ratios specified in claims 17-21; however Gudas et al does teach that dosages of the compounds vary based on several factors including the age, weight, condition of patient, etc. (p. 15, lines 15-23). It is obvious from the above teachings that Gudas et al expressly contemplates variation in the dosage amounts of the active agents and specifically acknowledges that such a matter was well within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the concentrations

and ratios of composition components that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

07May2009
CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645